**QUESTIONS FOR THE RECORD: Farzad Mostashari, National Coordinator for Health Information Technology, U.S. Department of Health and Human Services**

**"Health Information Technologies: Administration Perspective on Innovation and Regulation" – March 21, 2013**

**Committee on Energy and Commerce, Subcommittee on Oversight and Investigation, U.S. House of Representatives**

## Chairman Murphy

**Question 1:**

**Page 7 of your testimony notes that a November 2011 IOM report reported that "market forces are not adequately addressing the potential risks associated with the use of health IT." Has ONC experienced this? Does ONC believe that market forces are not adequately addressing patient safety or other risks?**

ONC believes that on the whole, the adoption of health IT has greatly improved patient safety by reducing medical errors and helping to standardize the way that care is provided, but we are mindful of the need to ensure that new systems are built and used in the safest possible manner. We believe market forces have already motivated a high level of safety in the industry, but there is opportunity for improvement. For instance, in 2014, certified EHR technology developers will be required to publicly identify a method of incorporating user-centered design that has a high likelihood of helping to prevent medical errors. Certified EHR technology developers will also be required to provide transparency regarding their approach to quality management systems.

In our draft Health IT Patient Safety Action and Surveillance Plan, we encouraged the industry to draft and enforce a voluntary code of conduct to improve safety practices, among other things. We will continue to monitor the industry's progress in addressing potential safety risks going forward.

**Question 2:**

**Page 8 of your testimony notes that ONC's draft plan on Health IT Patient Safety will recommend the inclusion of "safety requirements related to user-centered design ... and easier reporting of adverse events ... " Can you elaborate on the authority given ONC to either compel or recommend that these items be included? How will this be enforced, if ONC chooses to endorse this approach?**

The draft Health IT Patient Safety Action and Surveillance Plan (the Safety Plan) restates ONC's commitment to patient safety through the safe use of health IT. Prior to the Safety Plan's release, ONC had already adopted through rulemaking two safety-related 2014 Edition certification criteria for EHR technology. The first certification criterion requires that EHR technology presented for certification to any one of eight specific medication-related capabilities must have had user-centered design processes applied to them in order to be certified. The second certification criterion requires the identification of the quality management system followed and used in the design of the EHR technology. Given that these requirements are part of ONC's HIT Certification Program, they will be primarily enforced by the certification bodies ONC has authorized to perform certifications and, generally, by ONC in providing its overall program oversight.

**Question 3:**

**One of the main concerns about the push for the meaningful use of health IT is that we may be encouraging doctors and patients to rely more heavily on computers or the internet than face-to-face interaction. Do you have any evidence that the use of health IT is better or worse than interaction between a doctor and patient? Have any studies been done on the possibility this could decrease patient safety?**

Meaningful Use does not replace appropriate physician-patient interaction or in any way encourage virtual interaction when face-to-face is best warranted. Its application encourages more productive interactions by enabling physicians to make more fully informed point-of-care decisions and recommendations. Just as the advent of the telephone did not preclude, prevent, or disable the need for face-to-face interaction between the patient and his/her doctor, health IT and Meaningful Use provides yet another timely conduit for information exchange.

One of the most recently published reports by David Radley, et. al., describes how the use of computerized provider order entry (CPOE), a central component of Meaningful Use, decreases the likelihood of prescribing error by 48%.[1] ONC believes the application of this tool has tremendous potential to improve patient safety.

**Question 4:**

**Many complaints have been made about the problem of interoperability – health IT systems that cannot communicate with each other – in fact you were asked about this during questioning. What does ONC plan to do to finally solve this problem?**

Health IT and the secure exchange of information across providers are crucial to reforming the system. In 2014 EHRs will be significantly more interoperable because providers will have to demonstrate that they can exchange clinical information with other providers.

More specifically, starting in 2014 hospitals, doctors, and other eligible professionals that use certified EHR technology in Stage 2 of Meaningful Use will be able to share summary records across providers, send electronic prescriptions, electronically report clinical quality measures, and allow patients to view, transmit and download their health information. These advances, combined with the ongoing work ONC is doing to develop standards for health information exchange, will continue to drive increasing levels of interoperability over the coming months and years.

In addition, we are currently considering which policy levers might be able to strengthen the business case for the exchange of health information by making sure that different providers and vendors have the strongest possible incentive to share information. In March, ONC and CMS jointly issued a request for information (RFI) seeking public input on this issue. We have received over 200 comment letters from a wide variety of stakeholders, which we are reviewing.

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[1] Radley, D. C., Wasserman, M. R., Olsho, L. E. W., Shoemaker S. J, Spranca, M.D., Bradshaw, B. *Reduction in medication errors in hospitals due to adoption of computerized provider order entry systems. J Am Med Inform Assoc* 2013;20:3 470-476 Published Online First: 20 February 2013 doi:10.1136/amiajnl-2012-001241 (available at http://jamia.bmj.com/content/20/3/470.long) (last accessed 4/15/2013)

We are also encouraged that others have increasingly recognized the progress that is underway. At a recent hearing on HIT standards and interoperability that took place on November 14th, 2012 before the House Committee on Science, Space, and Technology, Subcommittee on Technology, all five witnesses stated that progress is being made on interoperability. Similarly, in an October, 2012 report on information sharing, the Bipartisan Policy Committee stated that a business case for electronic health information sharing is beginning to emerge, and also that the Meaningful Use Stage 2 requirements that take effect in 2014 largely address a majority of the information sharing needs that have been identified in clinician surveys.

**Question 5:**

**Does ONC see a problem with information sharing among psychologists or behavior health workers? Were Health IT incentives offered to this group? Why or why not?**

ONC has worked with the HHS Substance Abuse and Mental Health Services Administration (SAMHSA) to clarify the federal protections over substance abuse information in the context of health information exchange.[2] These efforts led to the publication of FAQs "Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE). Further, in September 2012, in partnership with other components of the Department of Health and Human Services (HHS) and with the Department of Veterans Affairs (VA), ONC, through its Data Segmentation for Privacy Initiative (DS4P) demonstrated that with proper standards in place, existing privacy laws and policies can be implemented appropriately in an electronic environment. Using standards identified in the DS4P Initiative, SAMHSA and the VA safely and securely transmitted a mock patient's substance abuse treatment records tagged with privacy metadata from one EHR to a different EHR system after electronically verifying that the mock patient had consented to the transmission.

Health IT incentives were not offered specifically to psychologists or behavioral health workers, and only mental health professionals who meet the definition of an eligible professional (EP) could qualify to receive EHR incentive payments under Medicare or Medicaid. The specific criteria for Medicare or Medicaid EPs can be found at the following link: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Getting_Started.html.

**Question 6:**

**The Health Insurance Portability and Accountability Act (HIPAA) protects the privacy of an individual's health information. How does ONC balance the requirements of HIPAA with the benefits of Health IT? What conflicts or barriers exist? In particular, are there any specific barriers or problems related to mental health records that ONC has encountered? Has ONC done any analysis or identified any problems related to HIPAA and the coming health insurance exchanges established by the Patient Protection and Affordable Care Act?**

ONC recognizes the importance of protecting the privacy of patient health information while at the same time encouraging greater use of health information technology (Health IT) in order to achieve significant improvements in areas such as health care quality and cost control. ONC works closely with other Health IT stakeholders to create a culture where ensuring the confidentiality, integrity and availability of electronic health information is seen less as a barrier to health information exchange than as a valued, shared cultural norm.

[2] http://www.samhsa.gov/about/laws/SAMHSA_42CFRPART2FAQII_Revised.pdf

With respect to HIPAA, ONC is not aware of any specific problems related to mental health records and the use of Health IT. For the most part, the HIPAA Privacy Rule treats mental health records in the same manner as any other protected health information (PHI). Under the Rule, a health care provider generally may use and disclose protected health information, including mental health records, for the key health-care related purposes of treatment, payment, and health care operations without obtaining the patient's express written authorization. While the Rule generally does require patient authorization for a covered health care provider to disclose psychotherapy notes (i.e., notes recorded by a mental health professional documenting the contents of a private or group counseling session which are maintained separately from the rest of the medical record), such notes are subjective to and for use by the originating provider and thus, access to the notes is rarely needed by other health care entities for treatment or other purposes.

Finally, with respect to the coming health insurance exchanges, ONC reviewed and contributed to the Patient Protection and Affordable Care Act (ACA) regulations, to help ensure that privacy, security, and data stewardship policies were appropriately incorporated into the final rules governing the new modes for exchanging and analyzing health information under the ACA. This effort addressed regulations governing: 1) accountable care organizations; 2) qualified entities that provide performance measurement services, 3) and the health insurance marketplace.

## Representative Johnson

**Question 1:**

**As an IT professional for 30 years, I understand the vital importance of IT architecture and having a roadmap to achieve the end state. As they say, if you don't know where you are going, any road will get you there.**

When ONC and CMS together published the original set of rules setting up the Electronic Health Record Incentive Program in 2010, we articulated long-term goals for the program that continue to serve as a useful roadmap as the program evolves over time (see 75 FR 44321). We continue to believe that certified EHR technology used in a meaningful way is one piece of a broader HIT infrastructure that will ultimately help reform the health care system and improve health care quality, efficiency, and patient safety. We look forward to working with you as we continue to pursue this vision.

**Question 2:**

**With regard to the Meaningful Use Program currently in place to guide implementation of electronic health record (EHR) systems, how is HHS ensuring that we aren't just collecting and digitizing data? Were the stages of Meaningful Use crafted with an IT architecture in mind that spans all stages to achieve a specific end? If so, then how?**

Starting with the first proposed rule on Meaningful Use Stage 1 issued in January 2010, HHS laid out its vision for what Stages 1, 2, and 3 would look like and focus on. With that vision in mind, we worked backward and charted an ambitious yet incremental course for the industry. We also took care to ensure that each Meaningful Use stage would build on the next. Thus, as an eligible provider progresses from one stage to the next they are asked to use the data in their EHR technology (and the technology itself) in specific ways that will help enhance care delivery and improve patient engagement. As we consider policy for Stage 3, we will continue to work toward the vision we laid out with a careful interest

in making sure that the experience eligible providers' gain through Stages 1 and 2 can be applied in Stage 3.

**Question 3:**

**Information must also be relevant and functional for the end user. How have you involved health care providers in the development of this road map to ensure that the time, money, and effort put into these systems will be worth their while and create an integrated, coordinated care system that streamlines their work? What concerns have these providers had with regards to EHR and Meaningful Use stages and how has HHS worked with these individuals to address them?**

Health care providers and other health professionals have been involved at every step of HHS's policy development processes for Meaningful Use. The HIT Policy Committee, which has made policy recommendations regarding Meaningful Use, includes healthcare providers that participate in the EHR Incentive Programs – for instance, the Committee's Meaningful Use Workgroup includes 8 medical doctors (including both co-chairs), 2 registered nurses, and a variety of other stakeholders who represent the health care industry more broadly. ONC and CMS openly solicit feedback from provider organizations during our rulemakings, and HHS employs several staff with significant clinical experience working with electronic health records. In both our Stage 1 and Stage 2 rulemaking processes, we introduced significant new flexibilities for providers into our final rules in response to public comments.

Some provider concerns are unique and specific to their practice/setting while others are more general. To educate providers about program requirements, HHS has produced a significant amount of downloadable education materials, increased the number of webinars and education sessions, and regularly communicated with provider associations to help spread the word. We have also devoted a considerable amount of resources toward the 62 Regional Extension Centers (RECs) that have been established across the country through cooperative agreements funded under the Health Information Technology and Clinical Health (HITECH) Act. The personnel that work in the RECs are local experts and work hand-in-hand with health care providers along every step of the way – from selecting an EHR to getting to meaningful use. We have also established a virtual infrastructure of communities of practice to enable healthcare providers to share best practices with each other and to communicate feedback directly to HHS.

**<u>Representative Butterfield</u>**

**Question 1:**

**Many rural parts of my congressional district are desolate and where the nearest primary care doctor can be an hour or more drive away. East Carolina University located in my district in Greenville, North Carolina has been operating a telemedicine program since 1992 – making it one of the oldest telemedicine programs in the world. Recognizing that there is a clear link between access to care and improved health, what other resources in addition to telemedicine are available now to link the rural elderly and indigent populations to healthcare providers like primary care doctors and physician's assistants? What is on the horizon?**

Medicare pays for certain telehealth services to beneficiaries in rural communities. Medicare pays for these services when they are furnished at specified originating sites that include physicians' offices, critical access hospitals, rural health clinics, and federally qualified health centers, and when those sites

are in either a rural Health Professional Shortage Area (HPSA) or a non-Metropolitan Statistical Area county.

In addition to telehealth, there are a number of programs available to help link the rural elderly and indigent populations to health care providers. HHS administers the Rural Health Outreach program, which provides grants to rural communities to test out new ideas and develop models for improving access to care. This program includes funding for rural health networks that help rural providers work together to build better systems of care.

As authorized under Section 3026 of the Affordable Care Act, HHS is also partnering with community based organizations and acute care hospitals under the Community-Based Care Transitions program to improve transitions of beneficiaries from the inpatient hospital setting to other care settings, to improve quality of care, to reduce readmissions for high risk beneficiaries, and to document measurable savings to the Medicare program. One of these partners, Access East Community-based Transitional Partnership, is located in Greenville, North Carolina.

**Question 2:**

**Recently, Congress passed legislation that requires the Department of Defense to expand telemedicine opportunities to service members regardless of whether they are on a base or in a home, and regardless of where the doctor is licensed. Are there ways we can use this model in other federal programs like Medicare to better expand access to care via telemedicine?**

The Center for Medicare and Medicaid Innovation is testing several projects related to increased use of telehealth. A project in Hawaii received a Health Care Innovation Award for telehealth-based home monitoring for very high risk patients with complex health care needs in order to prevent hospitalizations. A project in Wyoming received a Health Care Innovation Award to improve care coordination and communication with practitioners in ten rural Iowa counties using telehealth and web-based personal health records.

In addition, under the Affordable Care Act, accountable care organizations (ACOs) participating in the Medicare Shared Savings Program agree to coordinate care for beneficiaries, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.

**Question 3:**

**The VA has moved to mostly eliminate cost sharing on telemedicine, recognizing treating veterans at home is less expensive than treating them in a VA facility. For example: The Veterans Administration's home telehealth program has resulted in a 30 percent reduction in hospital administration and a 20 percent decrease in hospital stays. How can Congress build off this model and achieve similar outcomes in other federal healthcare programs?**

The Veterans Administration has long been a pioneer in the use of telehealth technology. In addition, the Health Resources and Services Administration has awarded funding for using tele-home care services. The CMS Center for Medicare and Medicaid Innovation (Innovation Center) has also funded a number of new models using telehealth technology. The Innovation Center is testing innovative payment and service delivery models that have the potential to reduce expenditures while preserving or enhancing the quality of care provided to Medicare, Medicaid, and CHIP beneficiaries. Participants in the testing of all of the models are encouraged to use health information technology, and we understand that they are using a variety of different technologies.

Currently, under the fee-for-service Medicare benefit, Medicare has the authority to pay for telemedicine services for beneficiaries in specified rural communities provided by specified providers. Section 1834(m) of the Social Security Act authorizes Medicare payment for telehealth services. The statute requires that the originating site for telehealth services be in an area designated as either a rural health professional shortage area, or a county that is not included in a Metropolitan Statistical Area. The statute lists certain services that are considered telehealth, but also allows for the addition of other telehealth services. CMS annually evaluates whether to add additional services to the telehealth benefit, and last year in the final rule for the CY 2013 Physician Fee Schedule, a variety of new services were added. Some of these new services include: alcohol and substance abuse and intervention services; annual alcohol misuse screening; annual depression screening; intensive behavioral therapy for cardiovascular disease; and intensive behavioral therapy for obesity.